

Minutes and Actions for Biologics Subteam Discussion (January 22, 2008)

Attendees:

K Hluchan, B. McGinty, M. Glavin, T. Cantu, S Stevens Miles, J Berger, D Joslyn, E Shen, D Oliviera, R Kalish, M Mehta, A Soslow, A Poteat

WIKI Link: <http://spl-work-group.wikispaces.com/Biologics>

Minutes:

Training Opportunities [<http://spl-work-group.wikispaces.com/Training>]

Debrief on Content of Label Submissions

- No particular issues to report. One observation – if sending test submissions through the ESG for eList, you use the ESG production system. And it is a good idea to send an e-mail to spl@fda.hhs.gov alerting Lonnie that there's a test submission being sent to eList.

UNII Codes for CBER Active Ingredients

- Sponsor communications containing UNII codes for currently active products are not being received as quickly as we hoped. Only one letter has been reported as being received so far.
Alert your regulatory representation to be 'on the lookout' for letters, as they may not realize that the UNII codes are needed for SPL files.

Immune Globulin Worksheet comments/examples

- Two subteam members have tried out examples against the worksheet
- General observations: a number of the characteristics on the worksheet are not found in the label text. Both examples require additional help from CMC and/or Regulatory groups.
- As with the Vaccines worksheet, this one – when finalized – will become either a new chapter or part of an existing chapter in the Substance Registration System Manual at the FDA.

[REMINDER] Submission of SPL Content of Labeling

- For the first 12 months of CBER content-of-labeling SPL submission: include SPL with Annual Report – even if there have not been changes. This will result in all relevant products having SPL on file at the FDA within one year after implementation. Consult your Reviewer if there may be a delay in submitting an SPL.
- Draft SPL will be reviewed whether or not it has all UNII codes. If the codes are available, fill them in, as this facilitates the review process.
- Final SPL will not pass validation without UNII codes. It will not be posted on the DailyMed site without them.

- For eCTD submissions, SPL is placed in Module 1, section 14 (Labeling) in Draft Labeling or Final Labeling as appropriate.
- For other electronic submissions, make sure that the SPL content of labeling files are in their own \SPL folder. This folder must contain the *.xml file and any accompanying figures.
- Drug Listing and Establishment Registration SPL is required starting June 1, 2009. Prior to that, sponsors are being encouraged to submit these SPL through the eList Pilot Program.

Actions:

All Sponsor Reps:

If you are submitting SPL with upcoming CBER submissions for new, not-yet-approved products, and need UNII codes for your ingredients, alert the Review Division that UNII assignments are needed for one or more active ingredients and moieties.

Sponsor Reps with Immune Globulin products:

Continue to identify how your product(s) would be characterized.

Next Meeting: February 26, 2009.